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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,153	09/13/2000	Matthew A. Howard III	UIOWA-8PAD1	7887

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EXAMINER
THOMPSON, KATHRYN L

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/661,153	HOWARD III, MATTHEW A.
	Examiner	Art Unit
	Kathryn L Thompson	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/22/02* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-10, 12-15, 40-44, 52-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10,12-15,40-44 and 52-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53, 71, 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Corrales (US 3,941,119). Corrales discloses a macrocatheter and a plurality of microinfusion catheters disposed within the macrocatheter, wherein at least one microinfusion catheter comprises a plurality of drug delivery ports and is configured to receive a drug and infuse the drug into a tissue of a patient (See Figure).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 40, 52-56, 58, 71, 77, 78, and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al (US 5,720,720) in view of Corrales (US 3,941,119). Laske et al discloses all of the claimed limitations except a plurality of microinfusion catheters and a macrocatheter for housing the plurality of microinfusion

catheters. Corrales discloses a plurality of microinfusion catheters and a macrocatheter (See Figure). It would have been obvious to one with ordinary skill in the art to use the teachings of Corrales to modify the invention of Laske et al in order to create a drug infusion assembly that has multiple microinfusion catheters carried by a macrocatheter so as to have better control over medicating different sites in the hypothalamus. By using more than one microinfusion catheter, more medication could be delivered to different sites at the same time.

Claims 9, 10, 59, 74, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al in view of Corrales, further in view of Tillander (US 3,674,014). Laske et al and Corrales teach all of the claimed limitations except a macrocatheter including a magnet located at the distal end of said macrocatheter. Tillander teaches a macrocatheter (Figure 2) including a magnet located at the distal end of said macrocatheter (4b). Tillander discloses that a magnetic field acts with the magnetic in allowing for the placement of the macrocatheter into a selected artery (Column 3, Lines14-31). It would have been obvious to one with ordinary skill in the art to use the teachings of Tillander to modify the invention of Laske and Corrales in order to create a macrocatheter with a magnetic that would allow for placement of the macrocatheter to a specific location within the patient's brain.

Claims 12, 42, 43, 44, 57, 60, 61, 63, 64, 65, 66, 68, 69, 70, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al in view of Corrales, further in view of Heil, Jr. (US 5,041,107). Laske et al and Corrales teach all of the claimed limitations except a 1) drug reservoir/pump that is capable of pumping a drug at

a variable rate, 2) the plurality of microinfusion catheters that are configured in such a way that each of the plurality of drug delivery ports can be independently controlled, 3) monitoring electrodes, and 4) a controller functionally coupled to the plurality of microinfusion catheters. Heil, Jr. teaches 1) drug reservoir/pump that is capable of pumping a drug at a variable rate (Column 5, Lines 39-42), 2) the plurality of microinfusion catheters that are configured in such a way that each of the plurality of drug delivery ports can be independently controlled (Column 3, Lines 54-55, and Column 4, Lines 13-30), 3) monitoring electrodes (22 and 26), and 4) a controller functionally coupled to the at least one microinfusion catheter (24 or 28). With regards to Claim 12, Heil, Jr. discloses that due to Faraday's Law, the drug is infused at a rate that can be precisely controlled in order to obtain a desired dose rate (Column 4, Lines 24-30). It would have been obvious to one with ordinary skill in the art to use the teachings of Heil, Jr. to modify the invention of Laske et al and Corrales in order to create a drug reservoir/pump capable of pumping a drug at a variable rate, varying according to the amount of drug desired to be infused. With regards to Claim 42, Heil, Jr. discloses that the advantage of the delivery port being self-closing is to prevent ingress of blood or other tissue into the lumen of the microinfusion catheter. Therefore, this "self-closing" or independent closing of the drug delivery port prevents the possibility of catheter occlusion (Column 4, Lines 6-12). It would have been obvious to one with ordinary skill in the art to use the teachings of Heil, Jr. to modify the invention of Laske et al and Corrales in order to create a drug reservoir/pump wherein the at least one microinfusion catheter is configured such that each of the plurality of drug delivery

ports can be independently controlled. With regards to Claim 43, Heil, Jr. discloses that the polar relationship between the electrodes and the drug, powered by the pump (12), allows for the release of the drug into the bloodstream at a specific site (Column 4, Lines 16-24). It would have been obvious to one with ordinary skill in the art to use the teachings of Heil, Jr. to modify the invention of Laske et al and Corrales in order to create a drug infusion assembly further comprising monitoring electrodes to release a drug at a desired dose rate (Column 4, Lines 25-27). With regards to Claim 44, Heil, Jr. discloses that the controller on the microinfusion catheter serves as a connection between the pump and an electrode. The pump through the presence of the controller powers the electrode. It would have been obvious to one with ordinary skill in the art to use the teachings of Heil, Jr. to modify the invention of Laske et al and Corrales in order to create a drug infusion assembly with a controller functionally coupled to the at least one microinfusion catheter.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al in view of Corrales, further in view of Feingold (US 4,871,351). Laske et al and Corrales teach all of the claimed limitations except 1) a drug reservoir/pump capable of pumping a drug at a variable rate, the variable rate capable of being controlled percutaneously by a radio control unit, 2) a recharge valve for recharging said drug reservoir/pump with a drug, and 3) a recharge valve accessible percutaneously. Feingold teaches a drug reservoir/pump (8) capable of pumping a drug at a variable rate, and the variable rate capable of being controlled percutaneously by a radio control unit (1) (Column 5, Lines 34-58) and a recharge valve (9) accessible percutaneously

(Column 4, Lines 20-21). With regards to Claim 13, Feingold discloses that the radio control unit is a means for activating the pumping mechanism of the pump (Column 8, Lines 11-20). It would have been obvious to one with ordinary skill in the art to use the teachings of Feingold to modify the invention of Laske in order to create a drug infusion assembly wherein said drug reservoir/pump pumps a drug at a variable rate that is controlled by a radio control unit as a means for pump activation. With regards to Claims 14 and 15, Feingold discloses that the recharge valve, accessible percutaneously by syringe, is a refilling port that refills the drug reservoir/pump with a drug (Column 4, Lines 20-34; Column 4, Lines 60-65).

Claims 41, 53, 54, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al in view of Corrales, further in view of Sparks et al (US 4,940,588). Laske et al and Corrales teach all of the claimed limitations except an appetite-controlling drug for treating obesity. Sparks et al teaches an appetite-controlling drug for treating obesity (Column 4, Lines 23). It would be obvious to one with ordinary skill in the art to use the teachings of Sparks et alto modify the invention of Laske et al and Corrales to create a drug infusion assembly that contains a drug that is appetite controlling in order to treat obese patients.

Claims 63, 64, 65, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corrales in view of Heil, Jr. Corrales teaches all of the claimed limitations except the plurality of individually controllable drug delivery ports. Heil, Jr. teaches a plurality of individually controllable drug delivery ports (Column 3, Lines 54-55, and Column 4, Lines 13-30). Heil, Jr. discloses that the advantage of the delivery

port being self-closing is to prevent ingress of blood or other tissue into the lumen of the microinfusion catheter. Therefore, this "self-closing" or independent closing of the drug delivery port prevents the possibility of catheter occlusion (Column 4, Lines 6-12). It would have been obvious to one with ordinary skill in the art to use the teachings of Heil, Jr. to modify the invention of Laske et al and Corrales in order to create a drug reservoir/pump wherein the at least one microinfusion catheter is configured such that each of the plurality of drug delivery ports can be independently controlled.

Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corrales in view of Heil, Jr., further in view of Tillander. Corrales and Heil, Jr. teach all of the claimed limitations except a magnet configured to cooperate with an external magnetic field to guide the macrocatheter. Tillander teaches a macrocatheter (Figure 2) including a magnet located at the distal end of said macrocatheter (4b). Tillander discloses that a magnetic field acts with the magnetic in allowing for the placement of the macrocatheter into a selected artery (Column 3, Linesl4-31). It would have been obvious to one with ordinary skill in the art to use the teachings of Tillander to modify the invention of Corrales and Heil, Jr. in order to create a macrocatheter with a magnetic that would allow for placement of the macrocatheter to a specific location within the patient's brain.

Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corrales in view of Heil, Jr. Corrales teaches all of the claimed limitations except the plurality of drug delivery ports comprising individually controllable drug delivery ports. Heil, Jr. discloses the plurality of drug delivery ports comprising individually controllable drug delivery ports Heil, Jr. teaches a plurality of individually controllable drug delivery ports

(Column 3, Lines 54-55, and Column 4, Lines 13-30). Heil, Jr. discloses that the advantage of the delivery port being self-closing is to prevent ingress of blood or other tissue into the lumen of the microinfusion catheter. Therefore, this "self-closing" or independent closing of the drug delivery port prevents the possibility of catheter occlusion (Column 4, Lines 6-12). It would have been obvious to one with ordinary skill in the art to use the teachings of Heil, Jr. to modify the invention of Corrales in order to create a drug reservoir/pump wherein the at least one microinfusion catheter is configured such that each of the plurality of drug delivery ports can be independently controlled.

Claims 74 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corrales in view of Tillander. Corrales discloses all of the claimed limitations except a magnet on the macrocatheter configured to aid in the stereotactic placement of the macrocatheter in the tissue. Tillander teaches a macrocatheter (Figure 2) including a magnet located at the distal end of said macrocatheter (4b). Tillander discloses that a magnetic field acts with the magnetic in allowing for the placement of the macrocatheter into a selected artery (Column 3, Linesl4-31). It would have been obvious to one with ordinary skill in the art to use the teachings of Tillander to modify the invention of Corrales in order to create a macrocatheter with a magnetic that would allow for placement of the macrocatheter to a specific location within the patient's brain.

Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corrales in view of Tillander, further in view of Heil, Jr. Corrales and Tillander teach all of the claimed limitations except the plurality of drug delivery ports comprising individually

controllable drug delivery ports. Heil, Jr. discloses the plurality of drug delivery ports comprising individually controllable drug delivery ports Heil, Jr. teaches a plurality of individually controllable drug delivery ports (Column 3, Lines 54-55, and Column 4, Lines 13-30). Heil, Jr. discloses that the advantage of the delivery port being self-closing is to prevent ingress of blood or other tissue into the lumen of the microinfusion catheter. Therefore, this "self-closing" or independent closing of the drug delivery port prevents the possibility of catheter occlusion (Column 4, Lines 6-12). It would have been obvious to one with ordinary skill in the art to use the teachings of Heil, Jr. to modify the invention of Corrales and Tillander in order to create a drug reservoir/pump wherein the at least one microinfusion catheter is configured such that each of the plurality of drug delivery ports can be independently controlled.

Response to Arguments

Applicant's arguments with respect to claims 8-10, 12-15, and 40-44 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Thompson whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

KLT
November 3, 2002

MICHAEL J. HAYES
PRIMARY EXAMINER